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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/485,320 02/08/00 UCHIYAMA

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EXAMINER

HM12/0824

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MARX, T

ART UNIT

PAPER NUMBER

1651

DATE MAILED:

08/24/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No. 09/485,320	Applicant(s) Uchiyama et al.
Examiner Irene Marx	Art Unit 1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on Jul 27, 2001

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-12 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-12 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are objected to by the Examiner.

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) Notice of References Cited (PTO-892) 18) Interview Summary (PTO-413) Paper No(s). _____

16) Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) Notice of Informal Patent Application (PTO-152)

17) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) Other: _____

The election without traverse filed 7/27/01 is acknowledged. Claims 1-12 are being considered on the merits. Claims 13-32 are cancelled.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 8-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 is vague and indefinite in the recitation of "unidentified clinical syndrome in middle-aged to elderly women, inclusive of menopausal syndrome". To be with, the nature of "unidentified clinical syndrome in middle-aged to elderly women" is not ascertainable. In addition, the phrase "inclusive of" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention or not, and the resulting claim does not clearly set forth the metes and bounds of the patent protection desired.

Claim 10 is confusing in the recitation of "is a food form", since it is unclear what constitutes such a "form". In addition, with respect to "granules, capsules and tablets" these items appear to be pharmaceuticals rather than foods.

In claim 11, the term "in" appears to be missing prior to "a pharmaceutical".

Claim Rejections - 35 USC § 112

Claim 3 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ novel strains of *Bacteroides* and *Streptococcus* to obtain a specific product. The written description of that strain and the method of isolating is insufficiently reproducible. Therefore, a deposit for patent purposes is required. The specification discloses at page 9 that the strains were deposited at National Institute of

Biosciences and Human Technology of the Agency of Industrial Science and Technology under Budapest Treaty conditions.

For compliance with the rule, it must be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purpose of Patent Procedure (e.g. see 961 OG 21, 1977) and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent. MPEP 2403.

Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, date of deposit, name and address of the depository and the complete taxonomic description.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 6, and 8 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Chang *et al.* in light of Balows *et al.*

The claims are drawn to a composition comprising daidzein and a microbial strain which is capable of metabolizing daidzein to equol.

The cited reference discloses a composition comprising soybean milk and a microbial strain of *Bacteroides* which appears to be identical to the presently claimed strain and composition (see, e.g., page 1894, col. 2, paragraph 2-3) since the strain is comprised in feces and is capable of degrading a composition comprising the isoflavone daidzein to equol. That *Bacteroides* strains are comprised in feces is adequately demonstrated by Balows *et al.* See, e.g. bridging paragraph between pages 3597 and 3598. The referenced composition appears to be identical to the presently claimed composition and is considered to anticipate the claimed composition since it has substantially the same ingredients, i.e., it comprises daidzein and a microorganism which is of the same class as is found in the claimed composition and which appears to have substantially similar properties of being capable of degrading daidzein to equol. Consequently, the claimed composition appears to be anticipated by the reference.

In the alternative, even if the claimed composition is not identical to the referenced composition with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced composition is likely to naturally possess the same characteristics of the claimed composition particularly in view of the similar characteristics which they have been shown to share. Thus the claimed composition would have been obvious to those skilled in the art within the meaning of USC 103.

Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the reference, especially in the absence of evidence to the contrary.

Claims 1-10 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ishikawa *et al.*

The claims are drawn to a composition comprising daidzein and a microbial strain which is capable of metabolizing daidzein to equol.

The cited reference discloses a composition comprising soybean milk and a microbial strain of *Streptococcus* which appears to be identical to the presently claimed strain and

composition (see, e.g., Abstract) since it comprises isoflavones such as daidzein and equol. The referenced composition appears to be identical to the presently claimed composition and is considered to anticipate the claimed composition since it has substantially the same ingredients, i.e., it is in a food form and comprises fermented milk and a microorganism which is of the same class as is found in the claimed composition and which appears to have substantially similar properties of being capable of degrading daidzein to equol. The composition appears to have similar effectiveness because it is disclosed as having biological activity in the prevention of a disease of middle aged to elderly women, such as cancer. Consequently, the claimed composition appears to be anticipated by the reference.

In the alternative, even if the claimed composition is not identical to the referenced composition with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced composition is likely to naturally possess the same characteristics of the claimed composition particularly in view of the similar characteristics which they have been shown to share. Thus the claimed composition would have been obvious to those skilled in the art within the meaning of USC 103.

Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the reference, especially in the absence of evidence to the contrary.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ishikawa et al., taken with Halpin-Dohnalek *et al.*

The claims are drawn to a composition comprising daidzein and a microbial strain which is capable of metabolizing daidzein to equol.

As noted in the rejection supra, Ishikawa *et al.* discloses a composition comprising soybean milk and a microbial strain of *Streptococcus* which appears to be identical to the presently claimed strain and composition (see, e.g., Abstract) since it comprises isoflavones such as daidzein and the strain is capable of its degradation to equol.

The reference composition differs from the invention as claimed in that it is not provided in a pharmaceutical dosage form. However, Halpin-Dohnalek *et al.* adequately demonstrate that

compositions comprising live microorganisms are provided in capsule or tablet form (See, e.g., col. 4, lines 1-4).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the composition of Ishikawa et al. by providing the composition in tablet or capsule form as taught by Halpin-Dohnalek *et al.* for the expected benefit of providing the microorganisms, daidzein and other isoflavones in a measured form for the expected benefit of providing a composition that is practical and easy to store and which provides the proper level of active ingredients.

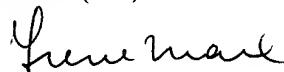
Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Irene Marx
Primary Examiner
Art Unit 1651